

REMARKS

Claims 23-34, as amended, are pending in this application for the Examiner's review and consideration. Independent claim 23 was amended to recite that the dermatological agent includes both an antimicrobial agent and an anti-inflammatory agent (*See e.g.*, original claims 1 and 23 and specification, page 5, line 30 to page 6, line 6) and to delete unnecessary functional language. Claims 25 and 27-28, which depend from independent claim 21, were simply amended to have proper antecedent basis. No new matter is added by these claim amendments so that there entry at this time is warranted.

THE CLAIMS

The present invention is directed to a method of treating, preventing, or managing a dermatological condition selected from the group consisting of a scalp condition, a hair condition, and a nail condition. The method involves administering to the patient a therapeutically effective amount of a composition comprising hydrogen peroxide, a hydrophilic moisturizing agent, a hydrophobic moisturizing agent, an exfoliant, an antimicrobial agent and an anti-inflammatory agent.

SUMMARY OF THE OFFICE ACTION

In the Office Action, claims 23-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, alternatively, under 35 U.S.C. § 103(a) as being obvious over published international application WO 91/02538 ("the '538 application").

The '538 application discloses a composition comprising a film forming protein and a reducing agent and, optionally, a reactive zinc salt, a cationic polymer, or a cationic or nonionic surfactant (*See, e.g.*, the '538 application, page 1, lines 1-7 and page 5, lines 16-22). The compositions may further comprise an oxidizing agent or an anti-oxidant (*See, e.g.*, the '538 application, page 5, lines 22-24). The compositions are allegedly useful for treating a variety of conditions (*See, e.g.*, page 1, line 29 to page 2, line 10). The film forming protein preferably contains cysteine residues (*See, e.g.*, the '538 application, page 13, lines 2-11) and the reducing agent reduces cysteinyl disulfide linkages in the protein to produce free thiol groups (*See, e.g.*, the

`538 application, page 15, lines 40-43). The cysteine residues allow the film forming protein to covalently bond to keratinous substrates (*See, e.g.,* the `538 application, page 13, lines 30-34). The reactive zinc salt, cationic polymer and cationic or nonionic surfactant stabilize the compositions and prevent the formation of malodorous side products (*See, e.g.,* the `538 application, page 16, lines 13-15 and 40-42; and page 18, lines 13-15).

THE REJECTION UNDER 35 U.S.C. § 102(B)

Claims 23-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by the `538 application. As the Examiner is aware, to establish anticipation under 35 U.S.C. § 102(b), a single prior art reference must disclose each and every limitation of a claim either expressly or inherently. *See Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1360 (Fed. Cir. 1998); *Standard Havens Prods., Inc. v. Gencor. Indus., Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991); *Jamesbury Corp. v. Litton Indus., Inc.* 756 F.2d (Fed. Cir. 1985); *American Hospital Supply v. Travenol Labs.*, 745 F.2d 1 (Fed. Cir. 1984) (holding that prior art is anticipatory only if every element of the claimed invention is disclosed in a single item of prior art). There must be no difference between the claimed invention and the reference disclosure as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Fdn. v. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986); *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444 (Fed. Cir. 1984) (holding that anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference). In addition, to anticipate, the reference must enable one of skill in the art to make and use the claimed invention. *In re Donahue*, 766 F.2d 531, 533 (Fed. Cir. 1985).

The `538 application does not anticipate claims 23-34, as amended, since the `538 application does not disclose each and every element of independent claim 23. The `538 application does not disclose a method of treating a dermatological condition by administering to a patient a composition that comprises each of (i) hydrogen peroxide, (ii) a hydrophilic moisturizing agent, (iii) a hydrophobic moisturizing agent, (iv) an exfoliant, (v) an antimicrobial agent, and (vii) an anti-inflammatory agent. Specifically, there is no disclosure or suggestion in the `538 application of a composition that includes *both* an anti-inflammatory agent and an

antimicrobial agent, much less in combination with hydrogen peroxide, a hydrophilic moisturizing agent, a hydrophobic moisturizing agent, and an exfoliant.

Since anticipation requires that each and every element of a claim must be taught by a single prior art reference, the '538 application does not anticipate claims 23-34. For the above reasons, Applicant respectfully requests that the rejection of claims 23-34 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

THE REJECTION UNDER 35 U.S.C. § 103(A)

Claims 23-34 were also rejected under 35 U.S.C. § 103(a) as being obvious over the '538 application. The proper inquiry for obviousness is whether the references disclose each and every feature of the claim and whether the references suggest the invention and provides one of ordinary skill in the art with a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988); *In re Royka*, 409 F.2d 981, 180 USPQ 580 (CCPA 1974); and M.P.E.P. § 2143.03. The '538 application does not render claims 23-34, as amended, obvious since the '538 application does not (a) disclose each and every feature of the invention, (b) suggest the invention, or (c) provide a reasonable expectation of success.

As discussed above, there is no disclosure or suggestion in the '538 application of a method of treating a dermatological condition by administering to a patient a composition that comprises each of (i) hydrogen peroxide, (ii) a hydrophilic moisturizing agent, (iii) a hydrophobic moisturizing agent, (iv) an exfoliant, (v) an antimicrobial agent, and (vii) an anti-inflammatory agent. Specifically, there is no disclosure or suggestion in the '538 application of treating a dermatological condition using a composition that includes *both* an anti-inflammatory agent and an antimicrobial agent, much less in combination with hydrogen peroxide, a hydrophilic moisturizing agent, a hydrophobic moisturizing agent, and an exfoliant. The antimicrobial agent inhibits the formation of and reduces the presence of microbes that cause redness, inflammation, and irritation of the skin, scalp, or nails (*See, e.g.*, Specification, page 16, lines 16-18) and the anti-inflammatory agent inhibits and suppresses inflammation on the skin and scalp (*See, e.g.*, Specification, page 15, lines 10-15).

Furthermore, there is no disclosure or suggestion in the '538 application that the anti-inflammatory agent and antimicrobial agent, should be administered in conjunction with the combination of a hydrophilic moisturizing agent, a hydrophobic moisturizing agent, and an exfoliant. The combination of the, hydrophilic moisturizer, hydrophobic moisturizer, and exfoliant advantageously helps the antimicrobial agent and anti-inflammatory agent penetrate the skin. The exfoliant functions by removing the dead or dying skin cells, enabling the skin to better absorb moisture from the atmosphere (*See e.g.*, Specification, page 12, lines 3-6), the hydrophobic agents prevent the loss of water from the skin (*See e.g.*, Specification, page 12, lines 6-8), and the hydrophilic agents moisturize the skin by absorbing moisture or facilitating hydration of the skin (*See e.g.*, Specification, page 12, lines 6-8). The combination of these three components (*i.e.*, the hydrophilic moisturizing agent, hydrophobic moisturizing agent, and exfoliant) is unexpectedly superior to using any one of these components individually. The hydrogen peroxide then further improves penetration of the antimicrobial agent and anti-inflammatory agent by cleansing the skin (*See e.g.*, Specification, page 10, lines 2-6). The '538 application fails to disclose or suggest a method of treating a dermatological condition that comprises administering both an antimicrobial agent and anti-inflammatory agent in conjunction with the combination of a hydrophilic moisturizer, a hydrophobic moisturizer, and an exfoliant; much less further combined with hydrogen peroxide.

Moreover, the '538 application does not provide a reasonable expectation that the combination of a hydrophilic moisturizer, a hydrophobic moisturizer, and an exfoliant, and hydrogen peroxide would act in a synergistic manner to provide enhanced efficacy of the antimicrobial agent and the anti-inflammatory agent in treating dermatological conditions. There is no disclosure or suggestion in the '538 application of this unexpected synergistic interaction.

The '538 application does not disclose or suggest a method of treating a dermatological condition using a composition that includes both an anti-inflammatory agent and an antimicrobial agent, much less in combination with a hydrophilic moisturizing agent, a hydrophobic moisturizing agent, an exfoliant, and hydrogen peroxide, or provide a reasonable expectation that such a method would have the unexpected results discussed above. Accordingly, the '538 application does not render claims 23-34 obvious. For these reasons,

Applicant respectfully requests that the rejection of claims 23-34 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

CONCLUSION

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

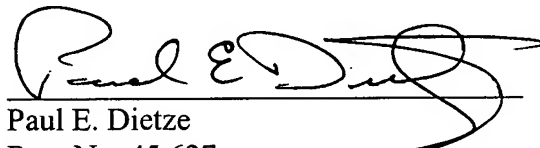
No fees are believed to be required for this submission. Should any fees be required, however, please charge those fees to our Deposit Account No. 50-0310.

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

Dated: March 18, 2004

By:


Paul E. Dietze
Reg. No. 45,627

MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 739-3000-p
(202) 739-3001-f
Customer No.: 009629